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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,931	11/16/2001	Kevin Qun Fang	4821-439-999	7960

20582 7590 10/20/2005

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EXAMINER	
KIM, VICKIE Y	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/987,931	FANG ET AL.	
	Examiner	Art Unit	
	Vickie Kim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,23 and 127-132* is/are pending in the application.

4a) Of the above claim(s) *19 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *127-132* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election of species acknowledged

Applicants' election of species, (S,S)-2-(3-chlorophenyl)-2-hydroxy-3,5,5-trimethyl-morphinol, with traverse is acknowledged. Applicant's traversal fail to reason the basis for traversal. As mentioned in previous office action, each species recited in claim 19 and 127 are patentably distinct species and thus, the election requirement is maintained and made FINAL.

Status of Application

1. Acknowledgement is made of amendment filed 3/26/04. Upon entering the amendment, the claims 1-7, 20-22 and 24-126 are canceled and the claim 19 is amended. New claims 127-132 are added.

2. Claims 19, 23 and 127-132 are now pending. The elected species are recited in claim 127, where the claims 127-132 are properly read on species elected. Thus, the elected claims 127-128 have been examined only to the extent that they read on use of the elected species in the claimed method. All remaining(or portions thereof) not drawn to the elected species are withdrawn from further consideration as being non-elected. The following rejections are made.

Response to Arguments

3. Applicant's arguments filed 3/26/04 have been fully considered but they are not persuasive. However, the scope changes made into the currently amended claims, the new ground(s) of rejection is necessitated and issued as following below.

Claim Objections

Claims 128, 130 and 132 are objected to because of the following informalities: there are inadvertent typographical error was found in claim 127 wherein (2S, 3S)-2-(3-chlorophenyl)-2- hydroxyl-3,5,5-trimethyl-2-morphinol is incorrectly typed whereas morpholinol is correctly spelled(see instant specification at page 2, lines 13-14. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 127-130 are rejected under 35 U.S.C. 102(e) as being anticipated by Morgan (US6391875, 6274579, 2003/0064988). Note: all these patents are children cases of US6391875 and disclosures therein are substantially same. Therefore, the examiner will use US'875 to represent all these cases.

The claims are drawn to a method of treating or preventing an affective disorders such as obesity, weight gain, or attention deficit hyperactivity disorder(ADHD) by administering a therapeutically or prophylactically effective amount of a bupropion metabolite such as (+)-(2S, 3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol.

Morgan et al(US'875) teaches a compound (+)-(2S, 3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol and its composition used for treating attention deficit hyperactivity disorder(ADHD), obesity or addiction to nicotine containing product(e.g. tobacco), see abstract and col.2, lines 21-63 and col.5, lines 36-52.

The critical elements required by the claims are well taught by the cited reference(s) and thus the claims are not patentably distinct over the prior art of the record and all the claims are properly included in this rejection as being anticipated.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 131-132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan (US6391875, 6274579, 2003/0064988) alone, or alternatively, in view of Howard et al(US6677378 or 6410736) .

Morgan's eaching is mentioned in 102 rejection above.

The claims 131-132 are requiring secondary active agent(e.g. SSRI, $5HT_3$ or nicotine).

However, it would have been obvious to one of ordinary skill in the art at that time of the invention was made to combine secondary active agent to improve the therapeutic efficacy because the combination drug therapy is known as standard drug regimen for the treatment of psychiatric conditions or other affective conditions, see extrinsic evidences PTO-892, for instance, Post et al(1997)) .

This one would have been motivated, with reasonable expectation of success, to apply combination drug therapy with SSRI, 5HT or nicotine which utilizes different underlying mechanisms where each drug's optimal dose can be lowered along with reduced side effects.

At any event, this combination drug therapy is routinely practiced in the treatment of affective disorders(see evidential documents, Howard et al (US 6410736 or US 6677378, see full text).

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 127-132 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/987930 due to the reasons set forth in previous office action because both inventions are drawn to the similar invention where the scoped of the invention is overlapping substantially. For instance, the claimed subject matter sharing the same scope(i.e. a treatment of affective disorders using (2S, 3S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this inal action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
Primary Patent Examiner
October 17, 2005
Art unit 1618